TURBICHEM RF

(Turbilatex method)

KIT NAME	KIT SIZE	CAT. NO
Turbichem - RF	1 x 50 ml	TRF000050D

GENUINE BIOSYSTEM

INTRODUCTION

Rheumatoid Factor (RF) is intended for Invitro quantitative determination of Rheumatoid Factor in human serum. Rheumatoid Factors (RF) are heterogeneous group of high molecular weight auto-antibodies of immunoglobulin isotypes IgM, IgA, IgG, and IgE. They are produced by plasma cells present at sites of issue injury, and may play a role in the regulation of humoral and cellular immunity and protection against invading microorganisms though the exact function of RF remains unclear. Studies have shown that both environmental and genetic factors can affect the synthesis of RF. RF levels are often elevated in patients with rheumatoid arthritis and Sjogren's syndrome, and could also rise in scleroderma, dematomyositis, Waldenstrom's disease, sarcoidosis, and systemic lupus erythematosus.

METHOD PRINCIPLE

The reagent consists of a suspension of latex particles of homogeneous size sensitized with anti-RF, capable of aggregation in the presence of RF. This aggregation process produces an increase in the size of the latex particles which in turn produces an increase in the Absorbance of the system.

KIT CONTENTS

R1 - RF Buffer	1 x 40 ml
R2 - RF Latex	1 x 10 ml
R3 - RF Calibrator	1 vial

The reagents when stored at 2-8°C are stable up to expiry date printed on the package. The reagents are stable for 30 days on board the analyser at 2-10°C. Protect from light and avoid contamination.

WORKING REAGENT PREPARATION AND STABILITY

Assay can be performed with use of separate R1-RF and R2-RF reagents or with use of working reagent. For working reagent preparation mix gently 4 parts of R1-RF with 1 part of R2-RF. Avoid foaming.

Stability of working reagent : 10 days at 2-8°C

CONCENTRATIONS IN THE TEST

RF Latex Reagent : Suspension of Latex particles sensitized with anti-human RF, sodium azide 0.9 g/L

RF Buffer Solution : Glycine buffer, pH 8.1, sodium azide 0.9 g/L

WARNINGS AND NOTES

The security statements are on the label. We advise to read MSDS before reagent manipulation.

Human sera used in controls have been found negative in the reaction with HBsAg and HIV I/II. However, they should be handled with care. On the other hand, reagents and controls are preserved with 0.09% sodium azide. Please, handled with care.

ADDITIONAL EQUIPMENT

- Automatic analyzer or photometer able to read at 630 nm
- Thermostat at 37ºC
- General laboratory equipment

SPECIMEN

Fresh sera or stored at 2 - 8ºC for no longer than 48 h. It is necessary to freeze the sample when the assay is to be carried out after that period of time. Discard contaminated or hemolyzed sera.

PLOTTING OF MULTIPOINT CURVE

The Turbichem RF is based on Non-Linear Reactions, hence it is strongly recommended to run Multi-standard mode to plot the Multi-point curve to have better accuracy and precise result.

Serial Dilution Step

	1st	2nd	3rd	4th	5th
Calibrator	100 µl	50 µl from 1st Tube	50 µl from 2nd Tube	50 µl from 3rd Tube	50 µl from 4th Tube
Normal Saline	0	50 µl	50 µl	50 µl	50 µl
Ratio of Dillution	Neat	1/2	1/4	1/8	1/16

PROCEDURE

These reagents may be used both for manual assay (Sample Start and Reagent Start method) and in several automatic analyzers. Applications for them are available on request.

Wavelength	630 nm
Temperature	37°C
Cuvette	1 cm

Pipette into the cuvette:

Reagent	Calibrator (C)	Test (T)
Working Reagent	1000 µl	1000 µl
Bring upto the temperature of determination. Then add		
Calibrator	10 µl	-
Sample	-	10 µl

Mix well, after about 10 sec. (37°C) read the absorbance A1 of the test (T) and calibrator (C) against air or water.After exactly 120 secs. (for all temperature) read the absorbance A2 of the test (T) and calibrator (C). Calculate ΔA/min. (A2 - A1) for the test and calibrator.

CALCULATION

RF concentration = ΔA (T) / ΔA(C) x calibrator concentration

REFERENCE VALUES

upto 20 IU/ml

It is recommended for each laboratory to establish its own reference ranges for local population.

QUALITY CONTROL

To ensure adequate quality control, each run should include assayed normal and abnormal controls. If commercial controls are not available it is recommended that known value samples be aliquoted, frozen and used as controls

PERFORMANCE CHARACTERISTICS

- **Sensitivity / Limit of Quantitation:** 2 IU/ml
- **Linearity:** up to 150 IU/,l. Samples that give higher concentration should be diluted in saline Nacl 0.9% (1+4) and the final result have to be multiplied by 5
- **Repetitivity:** as CV% 4.8%,
- **Reproducibility:** as CV% 8.7%,

- Specificity / Interferences

No interference was observed by Bilirubin (250 umol/l), Haemoglobin (10 g/L), Triglycerides (50 g/L), ASO (400 UI/ml). Heparin (12mg/dl), CRP (70mg/L). Other drugs and substances may interfere in the test (see Literatures)

WASTE MANAGEMENT

Please refer to local legal requirements.

LITERATURE

1) Anderson, B., Antigens associated with Rheumatoid Artritis, in Natelson, S., Pesce, A.J., Dietz, A.A. eds. Current Topics in Clinical Chemistry, V3: Clinical Immunochemistry. (1979). AA.CC. 176-190.
2) Johnson, P.M., Faulk, W.P., (1976). Clin. Immunol. Immunopathol., 6, 414-440 Taborn, J. D., Walker, S. E., (1979). Lab. Med., 10, 392 - 395.
3) Witherigton, R.H., Teitsson, I., Valdimarsson, H., Seifert, M.H. (1984).Ann. Rheum. Dis., 42, 679-685.
4) Winkles, J. W., Lunec, J., Gray, L. (1989). Clin. Chem. 35 (2), 303-307. Young DS. Effects of drugs on clinical laboratory tests, 5th ed. AACC Press, 2000.

SYSTEM PARAMETERS

Method	Fixed Time (2-Point)
Wavelength	630 nm
Zero Setting	Distilled Water
Temperature Setting	37° C
Incubation Temperature	37° C
Incubation Time	----
Delay Time	10 secs
Read Time	120 secs
No. of Reading	2
Interval Time	----
Sample Volume	0.01ml (10 ul)
Reagent Volume	1.0 ml (1000 ul)
Standard Concentration	Refer Standard vial
Units	IU/ml
Factor	----
Reaction Slope	Increasing
Linearity	150 IU/ml

IVD CE

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